NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
PUBLIC HEALTH ASSURANCE DIVISION

CERTIFICATE - IN VITRO TESTING WITH RADIOACTIVE MATERIAL UNDER GENERAL LICENSE

180 NAC 3-008.09 establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to possess certain small quantities of radioactive material for In Vitro clinical or laboratory tests not involving the internal or external administration of the radioactive material or the radiation therefrom to human beings or animals. Possession of radioactive material under 180 NAC 3-008.09 is not authorized until the physician, veterinarian, clinical laboratory, or hospital has filed Form NRH-17 and received from the Agency a validated copy of Form NRH-17 with a certification number.

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 180 NAC 3-008.09

3-008.09 General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing

1. A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 180 NAC 3-008.09, items 2. through 6., the following radioactive materials in prepackaged units for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

    a. Iodine-125, iodine-131, selenium-75, cobalt-57, and carbon-14 in units not exceeding 370 kBq (10 microcuries) each.
    b. Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 microcuries) each.
    c. Iron-59, in units not exceeding 740 kBq (20 microcuries) each.
    d. Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85 kBq (0.05 microcurie) of iodine-129 and 1.85 Bq (0.005 microcurie) of americium-241 each.

2. No person receives, acquires, possesses, uses or transfer radioactive material pursuant to the general license established by 180 NAC 3-008.09, item 1. until he/she has filed Agency Form NRH-17, "Certificate - In Vitro Testing with Radioactive Material Under General License", with the Agency and received from the Agency a validated copy of Agency Form NRH-17 with certification number assigned. The physician, veterinarian, clinical laboratory or hospital must furnish on Agency Form NRH-17 the following information and such other information as may be required by that form:

    a. Name and address of the physician, veterinarian, clinical laboratory or hospital;
    b. The location of use; and
    c. A statement that the physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in 180 NAC 3-008.09, item 1. and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

3. A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 180 NAC 3-008.09, item 1. must comply with the following:

    a. The general licensee must not possess at any one time, pursuant to the general license in 180 NAC 3-008.09, item 1. at any one location of storage or use a total amount of iodine-125, iodine-131, iron-59, cobalt-57 and/or selenium-75 in excess of 7.4 MBq (200 microcuries).

    b. The general licensee must store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

    c. The general licensee must use the radioactive material only for the uses authorized by 180 NAC 3-008.09, item 1.

    d. The general licensee must not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, the U.S. Nuclear Regulatory Commission, or any Agreement State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

    e. The general licensee must dispose of the Mock Iodine-125 reference or calibration sources described in 180 NAC 3-008.09, item 1.d. as required by 180 NAC 4-039 and 4-04.

4. The general licensee must not receive, acquire, possess, or use radioactive material pursuant to 180 NAC 3-008.09, item 1.:

    a. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 180 NAC 3-014.08 or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or any Agreement State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under 180 NAC 3-008.09 or its' equivalent, and

    a. Unless the following statement, or substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of Manufacturer

5. The physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital possessing or using radioactive material under the general license of 180 NAC 3-008.09, item 1. must report in writing to the Agency, any changes in the information furnished by him in the "Certificate - In Vitro Testing with Radioactive Material Under General License", Agency Form NRH-17. The report must be furnished within 30 days after the effective date of such change.

6. Any person using radioactive material pursuant to the general license of 180 NAC 3-008.09, item 1. is exempt from the requirements of 180 NAC 4 and 180 NAC 10 with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 180 NAC 3-008.09 item 1.d. must comply with the provisions of 180 NAC 4-039, 4-057, and 4-058.

INSTRUCTIONS

Submit this form in duplicate to the Department of Health and Human Services Regulation and Licensure, Public Health Assurance Division, 301 Centennial Mall South, P.O. Box 95007, Lincoln, Nebraska 68509-5007.

A certification number will be assigned and a validated copy of NRH-17 will be returned.

(Print or Type)

1. Licensee Information

Legal Name: (Physician, Veterinarian, Clinical Laboratory or Hospital) _____

Address: _____

_____

City, State and Zip+4 _____

Person Authorized to sign binding documents for the Licensee _____

2. I hereby apply for a Certificate Number pursuant to 180 NAC 3-008.09 for use of radioactive materials for:

[ ] a. Myself, a duly licensed physician authorized to dispense drugs in the practice of medicine, or a veterinarian licensed to practice veterinary medicine.

[ ] b. The above named clinical laboratory.

[ ] c. The above named hospital.

3. If place of use is different from address in Item 1, please give complete address:

4. Certification:

I certify that:

a. All information in this certificate is true and complete.

b. Appropriate radiation measuring instruments are available to carry out the tests for which radioactive material will be used under the general license of 180 NAC 3-008.09. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the radioactive materials.

c. I understand that Agency regulations require that any change in the information furnished on this certificate be reported to the Agency within 30 days from the date of such change.

d. I have read and understand the provisions of 180 NAC 3-008.09 of the Agency regulations; and I understand that compliance with those provisions is required as to all radioactive material which is received, acquired, possessed, used, or transferred under the general license for which this certification number is filed with the Agency.

_____

(Signature of Person listed in Item 1.) (Date)

4. To be completed by the Agency:

Certification Number _____ ***Date***_____

Radioactive Materials Program Manager_____

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NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
DIVISION OF PUBLIC HEALTH ASSURANCE
RADIOACTIVE MATERIALS PROGRAM

CERTIFICATION OF DISPOSITION OF MATERIALS

INSTRUCTIONS - (Use additional sheets where necessary.)
Type or Print except where indicated.
Retain one copy for your files and submit original application to: Department of Health and Human Services Regulation and Licensure, Division of Public Health Assurance, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 68509-5007.
Upon approval of this application, the applicant will receive a Radioactive Material License, issued in accordance with the requirements contained in Title 180, Regulations for Control of Radiation and the Nebraska Radiation Control Act.

1. Licensee Information

Licensee Number:_____

License Expiration Date:_____

2. Person to Contact Regarding this Application

_____

Telephone #:_____

Licensee Name and Street Address:

Applicant Name: _____

Address: _____

_____

City, State Zip+4 _____

Telephone #: _____

FAX#: _____

E-mail Address:

3. Materials Data

No Materials have ever been procured or possessed by the Licensee under this License.

All Materials procured and/or possessed by the Licensee under the License Number cited above have been disposed of in the following manner:

Transfer
Specify the date of the transfer, the name of the licensed recipient and the recipient's Agency, NRC or Agreement State license number.
Describe specific materials transfer actions and if there were radioactive wastes generated in terminating this license, the disposal actions, including the disposition of low-level radioactive waste, mixed waste, Greater-than-Class-C waste, and sealed sources, if applicable.

Disposed of directly by Licensee
Describe specific disposal procedures (e.g. decay in storage).

4. Other Data

Our License has not yet expired, please terminate it.
A Radiation Survey was conducted to confirm the absence of licensed radioactive materials and to determine whether any contamination remains on the premises covered by the license:

NO (Attach Explanation)

YES, the results:

Are attached

Were forwarded to the Agency on (Date)_____

4. **Other Data** *(Continued)*

Address all future correspondence regarding this license to:

Name:

Address:

City, State Zip+4:

Telephone #:

FAX#:

E-mail Address:

5. CERTIFICATION
(This item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services Regulation and Licensure, Title 180, Regulations for Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

Applicant Name From Item 1.

By: _____ *Date:* _____

Signature

Print Name and Title of certifying official authorized to act on behalf of the applicant